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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,953	04/19/2002	C. Frank Bennett	ISPH-0621	3434

36324 7590 09/23/2004

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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,953	BENNETT ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a compound comprising an 8-30 nucleotide sequence that hybridizes to a nucleic acid encoding a B7 protein and a method of using said compound.

Group II, claim(s) 18-23, drawn to methods of treating inflammatory or autoimmune disease.

Group III, claim(s) 24, drawn to a method of inhibiting a T cell response in antigen-presenting cells.

Group IV, claim(s) 25-30, drawn to methods of inhibiting allograft rejection.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I - IV is a compound comprising an 8-30 nucleotide sequence that hybridizes to a nucleic acid encoding a B7 protein and modulates the expression of said B7 protein. However, Dougherty et al. (US Patent 5,667,998, 1997) disclose ribozymes that hybridize to human B7-1 and B7-2 via 20 nucleotides of antisense RNA and cleave the B7 mRNA, reducing expression. See entire document, especially Example 3, columns 24-26.

Therefore, the technical feature linking the inventions of Groups I and IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is considered to be a compound comprising an 8-30 nucleotide sequence that hybridizes to a nucleic acid encoding a B7 protein and modulates B7 expression.

The special technical feature of Group II is considered to be a method of treating an inflammatory or autoimmune disease by modulating B7 expression.

The special technical feature of Group III is considered to be a method of inhibiting a T cell response in antigen-presenting cells by modulating B7 expression.

The special technical feature of Group IV is considered to be methods of inhibiting allograft rejection by modulating B7 expression.

Accordingly, Groups I-IV are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

Furthermore, should applicants elect to prosecute Group I, this group is subject to further restriction as follows. Claims 9 and 11 are subject to an additional restriction since they do not contain a proper genus/Markush. See MPEP 803.02. If the members of a Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the office to refuse to examine that which applicants regard as their invention, unless the subject matter in a

claim lacks unity of invention. See In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980) and Ex parte Hozumi, 3 USPQ2d 1059 (BD. Pat. Ap. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 9 recites SEQ ID NOs 228, 231, 234 235, 237, 238, 240, 241, 243, 247, 248, 250, and 251, all targeted to human B7-1. Claim 11 recites SEQ ID NOs 256, 257, 259, 263, 267, 269-275, 278, 280, and 282-285, all targeted to human B7-2. Although these antisense sequences each target and modulate a human B7 sequence, they are considered to be unrelated, since each sequence is structurally and functionally independent and distinct for the following reasons: each has a unique nucleotide sequence (i.e. structure) and therefore targets a different and specific region of human B7 nucleic acid. Upon binding to B7 nucleic acid, each antisense functionally modulates B7 expression to various degrees (per applicants' Tables 22 and 23 in specification). As such, the sequences in claims 9 and 11 are not considered to constitute a proper Markush/genus and are therefore subject to restriction. Furthermore, a search of more than one (1) of the sequences listed in claims 9 and 11 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) antisense sequence from claims 9 or 11. Note this is not a species election.
The inventions are distinct, each from the other because of the following reasons:

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1636